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ASX ANNOUNCEMENT

Telix Completes TLX250-CDx (Zircaix®) BLA Submission for Kidney Cancer Imaging

Melbourne (Australia) – 3 June 2024. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that it has completed the submission of a Biologics License Application (BLA) to the United States (U.S.) Food and Drug Administration (FDA) for its investigational radiodiagnostic PET[1] agent, TLX250-CDx (Zircaix®[2], ^{89}Zr-DFO-girentuximab), for the characterisation of renal masses as clear cell renal cell carcinoma (ccRCC).

The rolling BLA submission, initiated in December 2023[3] with timelines pre-agreed with the FDA, was based on Telix's successful global Phase III ZIRCON[4] study in ccRCC. The clear cell variant of renal cancer is the most common and aggressive sub-type of kidney cancer. The ZIRCON study met all co-primary and secondary endpoints, demonstrating a sensitivity of 86%, specificity of 87% and a positive predictive value (PPV) of 93% for ccRCC, including in small, difficult to detect lesions[5].

As part of the BLA submission process, Telix has requested a Priority Review under the eligibility criteria of the Breakthrough Therapy designation[6]. If granted, this would potentially support an expedited review time. If Zircaix®[2] is approved, TLX250-CDx will be the first targeted radiopharmaceutical imaging agent specifically for kidney cancer to be commercially available in the U.S. and further builds on Telix's successful urology imaging franchise.

James Stonecypher, Chief Development Officer at Telix, stated, "Completing the BLA submission for TLX250-CDx represents a significant milestone for Telix as we bring our Breakthrough investigational kidney cancer imaging agent closer to market as a non-invasive diagnostic for patients. We believe TLX250-CDx is a natural follow-on product to Illuccix® as it is targeted at the same clinical stakeholders, the urologist and urologic oncologist, and leverages the proven commercial and distribution infrastructure developed through the launch of Illuccix®."

TLX250-CDx International Expanded Access

As part of Telix's commitment to access to medicine, the Company has opened an expanded access program (EAP) in the U.S.[7], named patient programs (NPPs) in Europe, and a special access scheme (SAS) in Australia to allow continued access to TLX250-CDx outside of a clinical trial to patients for whom there are no comparable or satisfactory alternate options.

U.S. patients, or physicians who may have eligible patients in the U.S., can e-mail eap-americas@telixpharma.com or complete the form here for further information.

Physicians in Europe and Australia who may have eligible patients can email eap-emea@telixpharma.com and eap-apac@telixpharma.com, respectively, for further information about TLX250-CDx named patient access.

[1] Positron emission tomography.
[2] Brand name subject to final regulatory approval.
[3] Telix ASX disclosure 19 December 2023.
[4] Zirconium in Renal Cancer Oncology, ClinicalTrials.gov ID: NCT03849118.
[5] Telix ASX disclosures 7 November 2022.
[6] Telix ASX disclosure 1 July 2020.
[7] ClinicalTrials.gov ID: NCT06090331.

Telix's Policy on Offering Compassionate Use to Investigational Medicines can be downloaded at the following link.

For more information about ongoing clinical trials of TLX250-CDx, please visit https://telixpharma.com/our-portfolio/clinical-trials/

About TLX250-CDx (Zircaix®[2])

TLX250-CDx (Zircaix®[2]) is a PET diagnostic imaging agent that is under development to characterise indeterminate renal masses as ccRCC or non-ccRCC in a non-invasive manner. Telix's pivotal Phase III ZIRCON trial (ClinicalTrials.gov ID: NCT03849118) evaluating TLX250-CDx in 300 patients, of which 284 were evaluable, was completed in 2022 and met all primary and secondary endpoints, including showing 86% sensitivity and 87% specificity and a 93% positive-predictive value for ccRCC across three independent readers**Error! Bookmark not defined.**. We believe this demonstrated the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide an accurate, non-invasive method for diagnosing ccRCC. Confidence intervals exceeded expectations in all three readers, showing evidence of high accuracy and consistency of interpretation.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals and associated medical devices. Telix is headquartered in Melbourne, Australia, with international operations in the United States, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical and commercial stage products that aims to address significant unmet medical needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX).

Telix's lead imaging product, gallium-68 (^{68}Ga) gozetotide injection (also known as ^{68}Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the U.S. Food and Drug Administration (FDA)[8], by the Australian Therapeutic Goods Administration (TGA) [9], and by Health Canada[10]. No other Telix product has received a marketing authorisation in any jurisdiction.

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, announcements made to the ASX, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on X and LinkedIn.

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This announcement has been authorised for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.

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[8] Telix ASX disclosure 20 December 2021.
[9] Telix ASX disclosure 2 November 2021.
[10] Telix ASX disclosure 14 October 2022.

This announcement may contain forward-looking statements that relate to anticipated future events, financial performance, plans, strategies or business developments. Forward-looking statements can generally be identified by the use of words such as "may", "expect", "intend", "plan", "estimate", "anticipate", "outlook", "forecast" and "guidance", or other similar words. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements are based on the Company's good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect the Company's business and operations in the future and there can be no assurance that any of the assumptions will prove to be correct. In the context of Telix's business, forward-looking statements may include, but are not limited to, statements about: the initiation, timing, progress and results of Telix's preclinical and clinical studies, and Telix's research and development programs; Telix's ability to advance product candidates into, enrol and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities; the commercialisation of Telix's product candidates, if or when they have been approved; estimates of Telix's expenses, future revenues and capital requirements; Telix's financial performance; developments relating to Telix's competitors and industry; and the pricing and reimbursement of Telix's product candidates, if and after they have been approved. Telix's actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements. You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the ASX or on our website.

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